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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

DEBTORS' STATEMENT IN RESPONSE TO THE REPLY OF THE NAS CHILDREN AD HOC AND SUPPLEMENTAL DECLARATION IN FURTHER SUPPORT OF ITS REQUEST FOR ENTRY OF A COURT ORDER AUTHORIZING EXAMINATIONS PURSUANT TO FEDERAL RULES OF BANKRUPTCY PROCEDURE 2004 AND 9006

Purdue Pharma L.P. ("**PPLP**") and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**," the "**Company**," or "**Purdue**") submit this statement in response to the *Reply of the NAS Children Ad Hoc and Supplemental Declaration in*

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717), and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Further Support of its Request for Entry of a Court Order Authorizing Examinations Pursuant to Federal Rules of Bankruptcy Procedure 2004 and 9006 [Dkt. No. 2538-2] (the "**Rule 2004 Reply**"), in further objection to the NAS Children Ad Hoc Committee ("**NASC**")'s Rule 2004 Motion,[2] and respectfully state as follows:

Preliminary Statement

1. Despite being provided with vast amounts of responsive information, the NASC persists in demanding that the Debtors produce and search for more and more documents and make certain Debtor and even non-Debtor individuals available for deposition. The NASC's continued requests are unfounded. *First*, the NASC requests documents to support its claim that the Debtors are liable to the NASC's constituents for allegedly "hiding" data concerning the risks associated with opioid use during pregnancy, a baseless allegation and one that ignores the Court's prior statements which have made clear that these cases are not about litigating liability and that discovery of such issues should be narrowly tailored. *Second*, even if such evidence of causation were needed from the Debtors in order for the NASC to be able to establish its constituents' claims, the documents it seeks are not relevant to that purpose. The NASC demands production of rat and rabbit studies dated more than twenty-five years ago. But animal data is at best only an early indicator of how medicines may affect humans and cannot supplant the best evidence of how Purdue's opioids affect pregnant women and their fetuses—the intervening twenty-five years of data regarding human experience with these medicines, which best evidence the Debtors have made available to the NASC. *Third*, the Debtors have produced

[2] Except where otherwise indicated, capitalized terms used herein but not defined have the meanings ascribed to them in the Debtors' objection to the Motion [Dkt. No. 2155] (the "**Debtors' Objection**).

(or directed the NASC to) the available animal (and other requested) data—often multiple times,[3] including the animal studies that were included in FDA submissions already produced in these cases. To be sure, the vast bulk of the documents being sought have already been produced to the NASC in the "data room" for these chapter 11 cases, but the NASC seemingly is unwilling to expend the effort to locate and review them on its own. Nonetheless, the NASC continues to maintain—with little basis—that additional unsubmitted animal studies "must" exist.

2. The Debtors are not trying to hide evidence. To the contrary, as the Court recently acknowledged, the Debtors sharing of information in these chapter 11 cases has been unprecedented. (Mar. 24, 2021 Omnibus Hr'g Tr. 100:10-18 ("I know of no bankruptcy case . . . where there has been so much information provided to enable a set of claimants to evaluate a choice between settlement and its alternative litigation.").) Indeed, as the nearly year-long effort to meet and confer with the NASC demonstrates, the Debtors have repeatedly produced (or directed the NASC to already-produced) documents responsive to their never-ending and ever-expanding requests. At this point, the NASC should not be permitted to continue with these demands. As set forth in the Debtors' Objection and below, no good cause exists for the NASC's proposed Rule 2004 examination, and, thus, the Rule 2004 Motion should be denied.

Argument

3. The NASC argues that it does not have to show good cause because no "non-debtor objects to the examination." (Rule 2004 Reply ¶ 41.) This is false. (*Id.* (citing *In re*

[3] For example, the latest allegation of documents "hidden" from the NASC pertains to "Company Core Data Sheets," or CCDS. If, however, the NASC had reviewed the documents it has access to, rather than suggesting that the Debtors are somehow "hiding" documents, it would have realized that the CCDS are included multiple times in the productions, including in FDA submissions. Nevertheless, as a courtesy, on March 31, 2021, the Debtors provided the NASC with the Bates numbers for and copies of CCDS for Oxycodone Hydrochloride, Buprenorphine, Hydromorphone, and, although not named in the request, Hydrocodone Bitartrate (Hysingla). (McClammy Decl. ¶ 22.)

AOG Ent., Inc., 558 B.R. 98, 108 (Bankr. S.D.N.Y. 2016) ("The party seeking Rule 2004 discovery has the burden to show good cause for the examination it seeks, and relief lies within the sound discretion of the Bankruptcy Court.")).) Instead, a Rule 2004 movant must affirmatively establish good cause, and courts must bear in mind that the examination "should not be so broad as to be more disruptive and costly to the [debtor] than beneficial to the [creditor]." *In re SunEdison, Inc.*, 562 B.R. 243, 249-50 (Bankr. S.D.N.Y. 2017) (quotation omitted) (noting that "[t]he era of paper discovery in relatively small cases has given way to the discovery not only of paper but also of vast amounts of electronically stored information ("ESI"), possibly stored on outdated systems, on numerous personal computers and servers located throughout the world"). Thus, where, as here, with confirmation fast approaching, a court may deny a Rule 2004 motion because "extending the[] chapter 11 cases to allow an investigation of speculative claims may add significant costs that the Debtors' estates and their creditors will have to bear." *In re AOG Ent.*, 558 B.R. at 111. Moreover, where a creditor's claims, "while significant in face value, are small when viewed in the context of the chapter 11 cases," and where the debtor has already provided substantial amounts of discovery related to the requests—some of which could be made by every creditor in the case—additional discovery would not appear necessary to resolve any material issues in the chapter 11 cases. *Id.* The burden is especially high when "the information sought [is] by examination [of a witness.]" *In re Drexel Burnham Lambert Grp., Inc.*, 123 B.R. 702, 712 (Bankr. S.D.N.Y. 1991). The NASC has not met its burden here.

A. *The Scope of the NASC's Requested Examination Is Not Appropriate or Tailored to the Administration of These Cases or the Establishment of its Constituents' Claims*

4. As an initial matter, and as the Court knows, these cases are not about litigating the Debtors' liability. Yet, despite this Court's clear guidance that diligence in these cases

should not be used "simply [to] establish liability at a time when substantial amounts of value have already been offered" (Mar. 18, 2020 Omnibus Hr'g Tr. 93:18-21), and the months-long mediation that resulted in settlement of its constituents' personal injury claims, the NASC nonetheless continues to devote a substantial portion of its Rule 2004 Reply to doing just that. (Rule 2004 Reply ¶¶ 4, 17 (indicating the need to uncover evidence of the "Debtors' knowledge of casual risks of fetal exposure to its opioids and, separately, the delay in reacting to it exacerbating a public health crisis," and, "[o]n a grander scale," for evidence "relat[ing] to [the] Debtors' probity, integrity and honesty")).[4]

5. As for the other purported "needs" for this examination, the Debtors do not dispute that the "successful launch and implementation of the NAS Abatement Program" (Rule 2004 Reply ¶ 25) is of great importance, as demonstrated by the plan's $60 million commitment. But, as much as the NASC attempts to frame its requests as fulfilling that goal, historical *in vitro* and animal studies and the other information sought fall well short because they are irrelevant in light of decades of human experience. Similarly, the "evidence" that the NASC seeks (even if it existed) would not advance its ability to prepare its constituents' claims for submission to and to

[4] *See, e.g.*, *id.* ¶¶ 5 (noting that the NASC is "seeking production of evidence relating, referring or concerning issues surrounding Debtors' liability and medical causation of their injuries"); 16 ("It has been left to the NAS Children Ad Hoc to uncover information that is useful in understanding issues of causation of fetal opioid exposure and, as a consequence, the extent of Debtors' liability to NAS Claimants, causing undue hardship.").

The NASC also newly argues that "no discharge should be considered until and unless both the Debtors and those members of the Sackler Families desiring a court order releasing them from liability all satisfy their burden of demonstrating that all of them, without exception, have acted honestly and with integrity and utmost probity in all respects." (*Id.* ¶ 36.) While there will be a time and a place for the Court to determine whether the standard for granting third party releases in these cases is appropriate under applicable Second Circuit case law, the NASC's attempt at rewriting that standard in order to justify its purported need for Rule 2004 examination now is wholly unavailing. *See In re Transmar Commodity Grp. Ltd.*, No. 16-13625-JLG, 2018 WL 4006324, at *9 (Bankr. S.D.N.Y. Aug. 17, 2018) (explaining that "the fact that the [d]ebtor engaged in misconduct pre-petition and that . . . certain of its principals have pleaded guilty to crimes charged in the [i]ndictment" was not sufficient to justify a Rule 2004 request particularly where the requesting party was already in possession of at least 5,942 documents containing the relevant search phrase).

receive distributions from the personal injury trust contemplated to be established pursuant to the filed plan.[5] Moreover, it is no secret (and the Debtors' certainly did not, as the NASC suggests (Rule 2004 Reply ¶¶ 12-15) attempt to hide the fact) that there are risks associated with ingesting opioids during pregnancy—indeed, the Debtors' label for OxyContin carried express warnings of such risks while the full-prescribing information advised women who were, or were planning to become, pregnant to consult with their physician regarding potential effects since as early as 1996. (*See* Debtors' Obj. ¶ 14 (noting that a section of the 1996 OxyContin label was devoted to "Pregnancy" and discussed animal studies and the risk of birth defects, while pointing out that such studies are "not always predictive of human response" and that no "adequate and well-controlled" human studies exist).)

6. Beyond being far afield of the stated goals of these cases, the NASC has not and cannot show that there is any legitimate scientific or practical utility to the Debtors' sustaining the burden of the NASC's ongoing requests. *First*, research on rats and rabbits (which is fundamentally what the NASC wants) is never more meaningful than human experience—which now exists over decades. It is a basic principle of scientific research that testing in animals may be an effective early tool for exploring potential toxic effects of a drug before that drug is administered to humans. But animal data does not substitute for or supplant human experience once that human experience exists. Indeed, the toxicology reference on which the NASC relies (Rule 2004 Reply ¶ 31 n.18), actually indicates that toxicology is meant as an imperfect

[5] The NASC laments that it will not have "first notice of 'the evidence that the Claims Administrator may consider in making such determination'" until the summer when the plan supplement is filed. (*Id*. ¶ 1.) But the NASC has already been made privy to (and has commented on) the trust distribution procedures that are currently being crafted by the Ad Hoc Committee of Individual Victims and, ostensibly, it will continue to be so informed. (*See Mediators' Report* (Sept. 23, 2020), Dkt. No. 1716 ("The NAS Committee (with regard to personal injury claims) and others are participating in the drafting of the trust distribution procedures.").)

surrogate, designed to "predict" potential impacts of future human experience. It is a useful tool in the absence of human data—not despite it.[6]

7. *Second*, through its requests for twenty-five-year-old preclinical animal studies, the NASC essentially seeks to ignore the decades of human data that do not support the NASC's theory that maternal use of oxycodone results in long-term or permanent harm to developing humans.[7] As previously discussed (Debtors' Obj. ¶ 13), there already exists substantial human data looking at the effect of opioid use on fetal development over decades and repeatedly declining to find that OxyContin, specifically, or oxycodone, generally, causes fetal malformations, "birth defects" or other permanent fetal injuries. It is based on the breadth of published and peer reviewed data and the considered assessments of leadership entities, including the American College of Obstetrics and Gynecology ("**ACOG**"). For example:

- ACOG publicly maintains that there are "no known lasting physical or intellectual problems for babies born with NAS." ACOG, *Opioid Use Disorder and Pregnancy*, available at https://www.acog.org/womens-health/faqs/opioid-use-disorder-and-pregnancy.

- ACOG also notes that long-term effects of opioid exposure on cognitive development have been studied, but scientific experiments have not been able to replicate adverse outcomes. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy

[6] *See, e.g.*, Bracken, M.J.R. Soc. Med. 2009 Mar. 1, 102(3): 120-122 ("The concept that animal research, particularly that relating to pharmaceuticals and environmental agents, may be a poor predictor of human experience is not new."), *accessible at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746847/; Van Norman, G. Limitations of Animal Studies for Predicting Toxicity in Clinical Trials, JACC Basic Transl. Sci. 2019 Nov. 4(7): 845-854, accessible at https://www/ncbi/nlm/nih.gov/pmc/articles/PMC6978558.

[7] Indeed, in other contexts, the NASC's own experts have acknowledged that opioids can be appropriately prescribed and used during pregnancy. *In re Natl. Prescription Opiate Litig.*, 1:17-MD-2804, 2021 WL 320754, at *10 (N.D. Ohio Feb. 1, 2021), *reconsideration denied*, 1:17-MD-2804, 2021 WL 821512 (N.D. Ohio Mar. 4, 2021) (denying class certification of NAS guardians classes because, *inter alia*, the plaintiffs failed to adequately articulate what alleged harms would be typical among the putative class members and noting that "[p]laintiffs' expert concedes physicians may appropriately treat pregnant women with opioid medications").

- Similarly, ACOG has stated that use of opioid replacement therapy to treat addiction in pregnancy does not cause fetal harm. ACOG states: "Based on many years of research, opioid replacement medication has not been found to cause birth defects." ACOG, *Opioid Use Disorder and Pregnancy*, available at https://www.acog.org/womens-health/faqs/opioid-use-disorder-and-pregnancy.

8. In light of the weight of the current, peer reviewed data on NAS based on decades of human experience, the notion that the NASC's ability to implement the NAS Abatement Program and prove up its constituents' claims rests on its ability to continue its dissection of the Debtors for allegedly "hidden" rat and rabbit studies is scientifically, legally, and practically untenable. The NASC continues to suggest—ostensibly, through its purported "expert" whose declaration the NASC appears to have abandoned in its Rule 2004 Reply (*see* Decl. of Dr. Charles Werntz, Motion, Ex. F (**"Werntz Decl**.")))—that some of the information that it seeks could be related to or "may lead to" information relevant to the abatement program (Rule 2004 Reply ¶¶ 13, 25, 32), but Dr. Werntz's declaration is wholly insufficient.[8] Dr. Werntz offers no answer (let alone actual evidence) for how these studies suggest important, undisclosed evidence or contradict publicly available information. For example, Dr. Werntz claims that the "[s]tatements in Document E513_00046100 suggest that there are toxicological and scientific information that was excluded from the information that was shared with the medical community," (Werntz Decl. ¶ 5) and that additional information has "the potential to reveal potential impacts." (*id*. ¶ 8.) But Dr. Werntz—who is: (i) not a toxicologist; (ii) does not claim to have expertise in drug development or in the testing of drugs in non-human models, and (iii) does not claim to care for either pregnant women or infants—offers nothing of substance to back

[8] Because the Wertz Declaration does not comport with the rules for expert disclosure and contains nothing but conclusions offered without any support, it should not be accepted by the Court.

up the NASC's tenuous deductions, like what specific information the NASC would need to potentially make the difference in its clients' ability to assert their claims against the personal injury trust.[9]

9. Based on the (at best) tenuous connection that the NASC's requests could have to these cases or the NASC's constituents' claims—and in light of the extensive searches that the Debtors nonetheless have conducted to be helpful to the NASC (as described in Section B below)—the NASC's request that certain Purdue employees be made available for depositions is also not warranted.[10]

B. *The NASC Seeks Ever-Changing and Amorphous Discovery From the Debtors While Refusing to Review Documents Already Provided and Provide the Debtors With the Information Necessary to Run Additional Reasonable Searches*

10. Notwithstanding that the NASC is seeking information that does not fall within the scope of Rule 2004, the Debtors have (as they have in all aspects of these cases) sought to reasonably assist the NASC where they could by making information available to it without

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[9] While the NASC may ponder whether new science may emerge over time, bankruptcy proceedings are not laboratories for medical research. As frequently noted, "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 270–71 (S.D.N.Y. 2018) (citations and internal quotation marks omitted), aff'd sub nom. *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 982 F.3d 113 (2d Cir. 2020). In other words, the NASC needs more than its speculation to justify its demands for more discovery in these cases (particularly given the Debtors' continued cooperation with the NASC's ongoing informal requests)—but it is clear that there is none.

[10] Although not identified in the Rule 2004 Reply (Rule 2004 Reply ¶ 5), the NASC is also demanding that the Debtors make available for examination "a person from Spring[b]orn Laboratory, International Research and Development Corporation, Pharmakon Research International"—all non-Debtors—regarding "preclinical research and studies following GLP and [non-GLP] involving animals" in addition to any number of undisclosed topics. (McClammy Decl. ¶ 23.) But, it is a rudimentary discovery principle that the Debtors do not have control over making a third party's employees available for depositions. *Renssealer Polytechnic Inst. v. Apple Inc.*, No. 13-cv-633, 2014 WL 12586845, at *2 (N.D.N.Y. Apr. 21, 2014) (noting that "a non-party's deposition may only be compelled through the issuance of compulsory process, including a subpoena" and that there is no readily apparent "source of authority to order a party to produce a non-party for deposition"). Thus, to the extent that the NASC is seeking such relief from the Debtors, that is not an appropriate request with respect to a Rule 2004 examination of the Debtors.

All references to "McClammy Decl." refer to the *Declaration of James I. McClammy* filed contemporaneously herewith.

unduly burdening the Court or the estates with litigation over discovery issues. However, the Debtors fully expected that the NASC would also reasonably conduct its own diligence, which repeatedly has not been the case.

11. As an initial matter, the NASC's discovery requests have been continuously shifting targets that provide the Debtors little information from which to construct reasonable searches. (*See, e.g.,* Debtors' Obj. ¶ 1 n. 2.) Now, in its Rule 2004 Reply, the NASC seeks discovery with respect to three categories of information, only one of which (animal studies) is related to prior requests submitted to the Court for scientific studies (*see id.*)—while the other two differ entirely. In particular, the NASC now seeks for the first time: (a) "[a]ny and all versions . . . of Debtors' [CCDS]. . . for all synthetic opioid products manufactured by the Debtors including, but not limited to (1) Oxycodone Hydrochloride, (2) Buprenorphine, and (3) Hydromorphone"; and (b) "[a] copy and complete index of the contents of the Central Repository Stamford, CT., or any document evidencing the fate of Central Repository Stamford, CT., in addition to disclosure of the identities of all records custodians" that have knowledge, access, or responsibilities with respect to the Central Repository." (Rule 2004 Reply, Ex. D.)

12. However, the reasonable searches that the Debtors have conducted (as described in detail in the McClammy Declaration) make clear that the NASC already has access to the documents that the Debtors have been able to determine exist related to the topics that the NASC has identified.[11] Indeed, as demonstrated by the history of the parties' correspondence, and

[11] As detailed below, the NASC already has access to the CCDS, and the "Central Repository Stamford, CT" allegedly containing unsubmitted FDA studies does not exist based on searches the Debtors conducted in response to an informal discovery request made by the NASC in February.

reiterated in the Rule 2004 Reply, it is clear that the NASC may never be satisfied and its discovery requests will continue indefinitely.[12]

13. The Debtors have been engaging informally with the NASC for approximately a year on discovery issues—meeting and conferring no less than 13 times, exchanging related correspondence, consistently pointing the NASC to studies and documents it asserts it does not have or cannot find **but that often turn out to be already in its possession** (which raises the question of the extent of the NASC's own diligence in reviewing the documents already produced), and providing additional discovery to the extent the information has not already been produced and is within the Debtors' possession or control. (McClammy Decl. ¶ 2.)

(i) Request # 1: Preclinical Toxicology Studies

14. As a preliminary matter, the Debtors have already produced to the NASC the information related to preclinical (animal) toxicology studies that is available after extensive and reasonable researches, despite little useful cooperation from the NASC. Requests for this data were first made on April 17, 2020, when, despite no prior request for diligence in these cases, the Debtors received the NASC's first draft Rule 2004 Motion and request to meet and confer regarding various discovery issues (the "**April 2020 Draft Rule 2004 Motion**"). (*Id*. ¶ 3.) The April 2020 Draft Rule 2004 Motion contained five interrogatories regarding scientific studies (including toxicological studies) and disclosures made to the FDA, as well as four requests for production regarding documents related to the same scientific studies and that hit on eight search terms, including "Neonatal Abstinence Syndrome," "NAS," "infant," and "in utero." (*Id.*) After discussing the request with the NASC, the Debtors directed the NASC to specific Bates ranges in

[12] (*See, e.g*., Rule 2004 Reply ¶ 25 (noting that the NASC seeks "disclosure of other materials presently sought and to be sought); *id.* ¶ 32 n. 20 ("[T]he NAS Children Ad Hoc intends to seek additional discovery and nothing herein should be construed as a waiver to additional discovery upon parties and non-parties alike.").)

productions to which the NASC has access where it could find five categories of scientific documents that fell within its broad requests, including submissions to the FDA for OxyContin that described and contained data relating to studies in rats and rabbits as well as *in vitro* (test tube)—which, ostensibly, is where the NASC learned of such studies. (*Id*. ¶ 4.) Given the broad nature of certain requests for production, the Debtors were unable to provide specific Bates ranges for all requests. (*Id*.) However, the Debtors explained how the NASC could find the requested documents on its own simply by reviewing the Bates ranges provided in connection with other requests and conducting searches of the productions using titles, authors, cites, or key words. (*Id*.)

15. Although the documents produced to the NASC are contained in a "data room" for these chapter 11 cases to which the NASC has access, the NASC consistently states that it does not have reasonable access to certain documents contained therein and asserts that the Debtors should do the work to find the documents within the production. For example, when the NASC told the Debtors that it was unable to find certain Bates-stamped documents in connection with the above request, the Debtors sent the NASC a direct link to the already-produced documents. (*Id*. ¶ 5.) Similarly, in connection with an August meet and confer to resolve any outstanding issues from the April 2020 Draft Rule 2004 Motion, the NASC sent the Debtors a letter arguing that the Debtors' production of "tens of thousands of pages" of responsive documents was deficient because the Debtors needed to provide "additional coding of [the] bates ranges, including dates, authors, and descriptions of documents," which was, according to the NASC, necessary to help it with **its own review** of the productions. (*Id*. ¶ 6.) In other words, the NASC wanted a log describing all of the documents produced. The NASC again cited several studies and certain Bates-stamped documents that it was unable to locate, which the

Debtors either again provided from the already produced documents or, where applicable, noted that they were unable to locate the studies. (*Id.* ¶ 7.) The Debtors did not, however, undertake the burdensome task of creating a log describing all of the documents. In mid-November 2020, an almost identical sequence of events occurred—another draft Rule 2004 (without prior notice or discussion with the Debtors), a meet and confer, the Debtors' re-production of documents, and the NASC subsequent request for a log or "index" describing the documents in the production. (*Id.* ¶¶ 8-9.)

16. During a meet and confer following the filing of the Motion, where the NASC again requested preclinical toxicological studies, as well as "non-good laboratory practice" ("**non-GLP**") studies), the NASC finally agreed (with the Court's encouragement) to follow the parties' original agreed process for the NASC to provide search terms related to the scientific studies to run over the broad productions provided in these cases to the Creditors' Committee. The NASC's search terms returned approximately 264,000 Debtor documents. (*Id.* ¶ 12.) Without having reviewed—indeed, **before even receiving**—the documents from the Creditors' Committee that hit on the NASC's search terms, the NASC requested a meet and confer to discuss the results of the search terms. (*Id.* ¶ 13.)[13] With respect to the non-GLP scientific studies, the Debtors (i) pointed the NASC to the "non-GLP" study referenced in the Rule 2004 Reply as having "not been disclosed through testimony under oath," (Rule 2004 Reply ¶ 8),[14]

[13] The NASC also wished to discuss yet another **new** request for information concerning "discount card data," which resulted only in a goose-chase for patient-level data of birth mothers of NAS claimants—which Purdue does not maintain in the normal course—and lack of reasonable cooperation from the NASC, who has not provided the Debtors with the HIPAA releases necessary to ensure that any searches to gather what scattered patient information that may be available will not be in vain. (*Id.*)

[14] Notably, the NASC, apparently conceding that it already had access to the study that it once asserted the Debtors were "hiding" from disclosure in these cases, states in its Rule 2004 Reply that the issue now is not that the study has not been disclosed but that it "has not been disclosed through testimony under oath." However, it is unclear to the Debtors why "testimony under oath" is needed when the full study has been produced. Relatedly, the NASC ironically attempts to demonstrate the Debtors' lack of responsiveness by referencing a document that it admittedly

and (ii) again offered to search for additional studies that the NASC specifies with a reasonable level of detail. (McClammy Decl. ¶ 21.)

17. In filing the Reply, the NASC has seemingly rejected the Debtors' offer to resolve its outstanding request for additional studies without Court intervention. Instead of providing reasonable search details regarding the scientific studies it seeks, the NASC now (quite incredibly) demands that the Debtors make available for deposition non-Debtor employees from "Springhorn [*sic*] Laboratory, International Research and Development Corporation, [and] Pharmakon Research International," as well as "Purdue's Director of Drug Safety Evaluation, and a member of the Drug Risk Management Group." (*Id.* ¶ 23.) The Debtors engaged with the NASC in two additional meet and confers on March 15, 2021, and March 19, 2021—neither of which were successful in resolving the remaining issues. (*Id.* ¶ 24.) Indeed, the NASC continued to refuse to provide the Debtors with reasonable detail regarding the studies so that the Debtors could conduct additional searches, instead ironically asserting that it did not want to do the Debtors' work to find the allegedly "hidden" studies that only it believes exist and expanded its list of potential deponents to include "Purdue's Director of Pharmacovigilance, or similar" and "Purdue's Head of Regulatory Affairs." (*Id.* ¶ 24.)

18. In sum, the Debtors have expended significant estate resources responding to extensive and continuous inquiries from, and re-producing documents to, the NASC related to scientific studies (that, again, appear to have little material value to its constituents' claims or the NAS Abatement Program), while the NASC still has not completed its own review of the 264,000 documents from the Creditors' Committee production that hit on its search terms and

already had access to (Rule 2004 Reply ¶ 3)—an assertion made even more incredible in the context of the NASC's consistent refusal to provide the Debtors with search terms or custodians with which to conduct reasonable searches.

has flatly refused to engage in normal course discovery practices where large volumes of documents are at issue (i.e., reviewing documents identified through targeted search terms or custodians). The Debtors can think of no other reasonable approach to search for something that they have every reason to believe likely does not exist (i.e., scientific studies that have not already been made available to the NASC) than to use search terms and review the documents that hit on those terms—particularly in the era of ESI discovery. *In re SunEdison*, 562 B.R. at 250; *see* Rule 2004 Reply ¶ 2 (suggesting that the parties should engage in "pre-ESI discovery").

(ii) Request #2: The So-Called "Central Repository Stamford, CT"

19. On February 10, 2021, the NASC approached the Debtors with yet another discovery request—information regarding a so-called "Central Repository Stamford, CT" that it believes may contain relevant scientific studies. (McClammy Decl. ¶ 18.) Cites to volumes of the "Central Repository Stamford, CT" in produced documents apparently led the NASC to hypothesize that this referred to a standalone repository containing various scientific studies and/or scientific databases. (*Id*.) The Debtors conducted multiple searches (including through an email archive containing every email to and from the Company for the last fifteen to twenty years and an index of paper files) and engaged in discussions with current and former Purdue employees in the Company's regulatory group concerning a "Central Repository Stamford." (*Id*. ¶¶ 18-20.) As a result, the Debtors were able to determine that (i) the "Central Repository Stamford" may refer to old paper files submitted to the FDA (that have since been scanned into electronic files that the NASC has already received), (ii) a standalone "Central Repository Stamford" of un-submitted FDA documents does not exist now (if it ever did), and (iii) there is no repository of regulatory documents or scientific studies *other than* those submitted to the

FDA (which, if relevant, were already produced to the NASC). (*Id.*)[15] The Debtors were unable to determine why certain documents in the production have the naming convention "Central Repository Stamford, CT" with a reference to a volume number. But, it is clear that many of the references found in the production refer to the same 353-page document that is also marked as being a part of a "New Drug Application" that was submitted to the FDA, and which has been produced a number of times.[16] (*Id.* ¶ 18.) In addition to re-producing the documents that reference the "Central Repository Stamford" to the NASC, the Debtors offered to conduct additional reasonable searches if the NASC would provide a reasonable level of detail regarding the studies it seeks. (*Id.* ¶ 19.) The NASC still was not satisfied—instead, it refused to even review the documents produced to date without first receiving "a sworn statement" regarding the "Central Repository Stamford." (*Id.* ¶ 20.) The NASC, again, made clear that, rather than search for documents in the productions, it wanted the Debtors to produce a separate database where it could easily find all "relevant" scientific information not submitted to the FDA. (*Id.*) The Debtors' complete response regarding "Central Repository Stamford" sent to the NASC on March 2, 2021— including the entirely appropriate conclusion that, given the extensive searches and inquiries on this topic, the Debtors' view the issue as "closed"—is attached to the Rule 2004 Reply as Exhibit F.

20. In the end, it is apparent that a separate standalone "Central Repository Stamford" database containing alleged non-FDA-submitted scientific studies does not exist, and the Debtors cannot create such a database simply to assuage the NASC's misguided attempt at guesswork.

[15] To be clear, Purdue's regulatory group does maintain an electronic repository of documents submitted to the FDA in Stamford, Connecticut, and it is industry practice to include any studies in those submissions. However, there simply is no repository of information or studies not submitted to the FDA. (*Id.* ¶ 20.)

[16] The Bates numbers for those documents were provided the NASC. (*Id.*)

(*See, e.g.*, Rule 2004 Reply ¶¶ 18 (concluding that it "stands to reason" that there is a "body of relevant and material information" that the Debtors are, "[w]ithout justification, . . . seemingly[] unwilling to release" based on information that the NASC has access to only because of the Debtors' broad and unprecedented disclosures in these cases); 19 (conceding that the Debtors have already produced "documents containing entries explicitly referencing pre-clinical studies being conducted on their opioid drugs" but inextricably concluding that it "stands to reason that not all of the underlying studies and research has been disclosed to the NAS [Committee]"); 22 (listing, without any credible basis, potential forms that the "central repository may consist of").

(iii) Request #3: Purdue's Company Core Data Sheets

21. As an initial matter, the NASC appears to believe that the "Company Core Data Sheets" that are referenced in files submitted to the FDA are an invention specific to the Debtors meant to keep a "compendium of knowledge" secret. (Reply ¶¶ 9-15, 26.) This is incorrect and underscores that the NASC fundamentally does not understand how a pharmaceutical company works or what information it is looking for (let alone its relevance to its constituents' claims). Indeed, as even a simple internet search reveals, company core data sheets are used broadly within the pharmaceutical industry and are in no way unique to the Debtors.[17] Moreover, as explained in one of the CCDS attached to the Reply, a CCDS is a "summary of relevant core information on th[e] [applicable] product[s]" and is meant to "be used when [s]ummary of [p]roduct [c]haracteristics or other [p]roduct [d]ocuments are being prepared, or when information regarding th[e] product is being updated. (Ex. C-2, at 1, Suppl. Decl. of D.

[17] *See, e.g.*, *Company Core Data Sheets and Benefit-Risk Evaluations: A Drugmaker's Guide to Postmarket Safety Reporting*, FDA News (Aug. 2020), *accessible at* https://www.fdanews.com/products/60409-company-core-data-sheets-and-benefit-risk-evaluations-a-drugmakers-guide-to-postmarket-safety-reporting; Perfecting Your Company Core Data Sheets, Regulatory Info (Jan. 21, 2019), *accessible at* https://regulatoryinfo.org/perfecting-your-company-core-data-sheets/.

Creadore) For example, CCDS are often referenced in the periodic safety update reports that are submitted to the FDA (and, thus, referenced in the documents produced to the NASC). (*See, e.g.*, McClammy Decl. ¶ 25.)[18]

22. Notwithstanding the NASC's mischaracterization of the documents it seeks, the Debtors informed the NASC that a large number of CCDS have already been produced and suggested that it examine those documents. (McClammy Decl. ¶ 21.) In fact, upon further review of the productions to which the NASC has access, the Debtors have produced multiple copies of all the CCDS for Oxycodone Hydrochloride from 2000 through 2017, multiple copies of all the CCDS for Buprenorphine Base Transdermal System from 2001 through 2016, multiple copies of all the CCDS for Hydrocodone Bitartrate (Hysingla) from 2015 through 2017, and multiple copies of at least one CCDS for Hydromorphone Hydrochloride. (*Id.* ¶ 22.) In addition to pointing the NASC to these already-produced documents, the Debtors offered to (i) produce other relevant CCDS to the extent they have not already been produced and (ii) direct the NASC to CCDS in the productions if it still is unable to find them. (*Id.* ¶ 21.)

23. Based on the foregoing, it is clear that the issue here is not lack of information provided by the Debtors but rather a lack of effort by the NASC to (i) review the information provided and (ii) engage with the Debtors in a productive way by describing with a reasonable

[18] The "evidence" derived from the CCDS that the NASC asserts demonstrates that the Debtors attempted to keep NAS-related opioid risks hidden is entirely unavailing. First, the "Sturm 2009 Clinical Statement" (Rule 2004 Reply ¶¶ 12-13) does not discuss opioid use in pregnant women or the impact of opioid use on fetal development. Rather, it discusses opioid use for women who are breast feeding (particularly short term for pain post caesarean delivery), as maternally-ingested opioids were known to pass through to breast milk. (*See* PPLPC056000665635, at 10, Suppl. Decl. of D. Creadore, Ex. C-3 (referencing the Sturm 2009 Clinical Statement at footnotes 32 and 33)). Those references are not surprising given that warnings about using opioids during lactation were in the FDA-approved product label as far back as 1996. Second, the NASC's reference to two public editions of a pregnancy and lactation reference guide that can be located online as evidence of the Debtors' withholding of critical risk information is nonsensical. (Rule 2004 Reply ¶¶ 14-15.) Moreover, those guides also relate to breastfeeding recommendations and "human data suggest[ing] [r]isk in 3rd trimester" from hydromorphone being "excreted into breast milk" that is self-evidently not evidence of harms caused during fetal development that would cause physical malformations or other birth defects. (*Id.* ¶ 15.)

level of detail what information it believes it does not have, rather than its continued attacks alleging that the Debtors are "hiding" information. The NASC cannot, in good faith, assert that the Debtors are "withholding information," "depriving NAS Claimants" of information, or "lock[ing]" away "an asset," when it refuses to review the information that has been provided. (Rule 2004 Reply ¶¶ 19, 17, 32.) Against that backdrop, the already frail argument that documents provided by the Debtors "strongly suggest[]," "lead to a presumption," or "stand[] to reason" that additional, undisclosed information is within the Debtors' possession, custody, or control, falls entirely flat. (*Id*. ¶¶ 8, 16, 18.)

24. After nearly a year of discussions regarding discovery requests that lack any reasoned direction or specificity from the NASC—and are only tangentially related to these cases (at best)—it is apparent that Court intervention is needed so that Debtors can put an end to this gratuitous "scavenger hunt" (*Id*. ¶ 2) disguised as Rule 2004 discovery and focus on plan confirmation and shepherding these cases toward final resolution.

Conclusion

For the reasons set forth above and in the Debtors' Objection, the Debtors respectfully request that the Court deny the Motion.

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Dated: April 1, 2021
New York, New York

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